1645

PATENT

Attorney Docket No.: 8830-25

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent application of Camilo Anthony Leo Selwyn Colaco	:	Group Art Unit: 1645
Serial No.	10/049,704	:	Examiner: J. E. Graser
Filing Date:	May 16, 2002	:	Conf. No.: **7595**
For:	Stress-Proteins From Extra-Cellular Pathogens As Vaccines Against Infectious Agents	:	

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Restriction Requirement dated October 2, 2003. Per the petition and fee submitted herewith, Applicant invokes the benefit of 37 C.F.R. 1.136 to extend the period for responding by four months, to March 2, 2004. A check for $740.00 is included to cover the fee for the extension of time. No further fee is believed due for the filing of this paper. However, if a further fee is due, kindly charge deposit account 50-0573. Please credit any excess to the same account.

CERTIFICATE OF MAILING
UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

BY Susan Pasuk SUSAN PASUK

DATE: March 2, 2004

Response to Restriction Requirement

Applicant elects Group II (claims 10-14) ***with traverse***. Reconsideration of the Restriction Requirement, to the extent discussed below, is respectfully requested in view of the following remarks.

The present claims are restricted into three groups:

Group I (claims 1-9 and 11), drawn to a method for producing a vaccine containing an immunogenic determinant, in which the immunogenic determinant is a complex of stress proteins and antigenic fragments from an extracellular pathogen that has been exposed to a stress-inducing stimulus[1].

Group II (claims 10-14), drawn to a vaccine containing an immunogenic determinant, in which the immunogenic determinant is a complex of stress proteins and antigenic fragments from an extracellular pathogen that has been exposed to heat, and to a method of treating an animal with the claimed vaccine. (Applicant believes that the Examiner mistakenly included claim 11 in the Group II claims, and that Group should consist of claims 10 and 12-14.)

Group III (claim 15), drawn to a method of eliciting an immune response in an animal in response to infection by an intra-cellular organism, comprising administering a vaccine containing an immunogenic determinant. The immunogenic determinant is a complex of stress proteins and antigenic fragments from the intra-cellular organism, which are produced by exposing that organism to external stress stimuli or by genetically modifying that organism so that synthesis of the protein/antigen fragment complexes is constitutive.

The claims of Groups I and II relate, respectively, to a process for making a vaccine, and to the vaccine made by the claimed process and methods of using the claimed vaccine. For the reasons discussed below, the claims of Groups I and II have unity of invention, and should be rejoined for examination on the merits.

The Examiner correctly acknowledges that the present application should be considered under the PCT Unity of Invention standard, but appears to have (at least to some extent) subjected the claims U.S. restriction practice. See, for example, pg. 3 of the

[1] The proteins induced by heat stress are the same proteins induced by stress generally; see pg. 1, ln. 31 to pg. 2, ln. 6 of the present specification.

Restriction Requirement, where the Examiner states in the last sentence of para. 2, "Groups I-III do not relate to a single general concept and are unrelated *as they contain different method steps, different modes of operation, and comprise different products*" (emphasis added). The latter part of the quoted passage is the U.S., rather than the PCT, standard.

MPEP § 1893.03 states that prosecution of an international application which enters the national stage in the U.S. under 35 U.S.C. § 371(c) "proceeds in the same manner as for a domestic application with the exceptions that . . . (B) unity of invention proceeds as under 37 C.F.R. § 1.475," which is governed by PCT Rule 13. Unity of invention under PCT Rule 13 is satisfied when there is a technical relationship among those inventions defined by the claims which involves "one or more of the same or corresponding special technical features." This unifying special technical feature is that which defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. PCT Rule 13.2 and the PCT Administrative Instructions, Annex B, Part 1(b).

Where a single patent application contain claims of different categories, the claims have unity of invention when all claims contain a special technical feature, and the claimed manufacturing process is specifically adapted to produce the claimed product. A process is "specifically adapted" for the manufacture of a claimed product when that process inherently results in the product. PCT Administrative Instructions, Annex B, Part 1(e)(i). According to the PCT Administrative Instructions, Annex B, Part 1(e)(iii), "[t]he words 'specifically adapted' are not intended to imply that the product could not also be manufactured by a different process." Thus, the Examiner need only consider whether claims of different categories contain the same or corresponding special technical feature, and whether the claimed process of manufacture inherently produces the claimed product.

Here, the special technical feature of the Group I process claims and the Group II product and method of use claims is the immunogenic determinant, which comprises a complex of stress proteins and antigenic fragments from an extracellular pathogen that has been exposed to a stress-inducing stimulus such as heat. All claims in Group I and II contain this feature. Also, performing the method recited in independent claim 1 necessarily results in the product of claims 10, 12 and 13[2], showing that the Group I methods are

[2] As the proteins produced by heat shock are the same produced by stress generally (see footnote 1), the product of claim 10 necessarily (*i.e.*, inherently) results from the claim 1 process.

"specifically adapted" for producing the claimed vaccine. Thus, the Group I and II claims have unity of invention.

The present case is analogous to Example 1 of the PCT Administrative Instructions, Annex B, Part 2(I), which illustrates independent process, product, and method of use claims that have unity of invention. In this Example, three independent claims are given: Claim 1 to a method of manufacturing substance X (represented in the present case by the immunogenic determinant); claim 2 to substance X; and claim 3 to the use of substance X. Unity exists between all three claims because all contain the special technical feature of substance X in common.

The Examiner alleges on pg. 3, para. 2 of the Restriction Requirement that the special technical feature is the particular set of method steps used to produce the vaccine composition of claim 11, and that these steps are not required to produce the vaccine of the Group II claims. However, as discussed above, the fact that the claimed product could perhaps be produced by another method does not prohibit the process of manufacture and product claims from being examined in the same application under PCT Rule 13. All that is required is that the claimed manufacturing process inherently produce the product. Here, the Group I process claims could not produce anything but the vaccine of claims 10, 12 and 13. Since both Group I and II claims possess the same special technical feature, the Group I and II claims have unity of invention.

Moreover, Example 7 of the PCT Administrative Instructions, Annex B, Part 2(I) shows that claimed method steps which produce a certain characteristic, and the characteristic itself recited in a product claim, can constitute the "same or similar special technical feature." In this Example, claim 1 is directed to a stainless steel composition of a certain yield strength. Claim 2 is directed to a process of manufacturing a stainless steel composition of the same yield strength, but the yield strength is not specified. (According to Example 7, the specification indicated that the process would produce the critical yield strength.) The process steps which produce the critical yield strength, and the recitation of the yield strength in the composition claim, are considered to be the same special technical feature and thus the claims have unity of invention.

Here, method claim 1 recites steps which produce a vaccine containing complexes of heat-shock proteins and antigen fragments as the immunogenic determinant. Claim 10

recites a vaccine containing complexes of heat-shock proteins and antigen fragments as the immunogenic determinant. The claim 1 process steps, and the recitation of the immunogenic determinant in claim 10, are therefore the same special technical feature.

Finally, Applicant notes that unity of invention was found during international phase of this application; see the International Search Report dated February 16, 2001 and the International Preliminary Examination Report issued on November 26, 2001.

Because all claims of Groups I and II have the same special technical feature, and the claimed product is inherently made by the claimed Group I process, these claims have unity of invention. Applicant requests that the Group I and II claims be rejoined for examination on the merits.

Respectfully submitted

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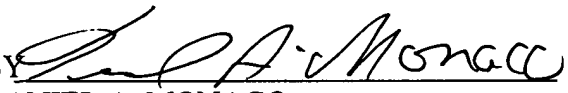
BY 

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